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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ROBINSON, B

ART UNIT

PAPER NUMBER

1625

DATE MAILED:

09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/854,694

Applicant(s)

Moloney Et. Al.

Examiner

Binta Robinson

Art Unit

1625

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☐ Responsive to communication(s) filed on \_\_\_\_\_

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-25 is/are pending in the application

4a) Of the above, claim(s) 3, 7, 10-14, and 17-20 is/are withdrawn from consideration

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1, 2, 4-6, 8, 9, 15, 16, 21, and 23-25 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some\* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Election/Restriction***

1. Claims 1-19, 24-25 are generic to a plurality of disclosed patentably distinct species comprising R1-R3, A, and B. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Marrienne Armstrong on 9/4/01 a provisional election was made with traverse to prosecute the invention of Diethyl 2--phenyl--(3-picolyl) malonate, claim 15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3, 7, 10, 11, 12, 13, 14, 17-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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The election of species will now be used as a reference point to create a natural genus under the guidelines of 3 U. S. C. 121.

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 2, 4,5, 6, 8, 9, 15, 16, 21-25 drawn to the formula I in claim 1 where the radical A is (CH<sub>2</sub>)<sub>0-5</sub>, R<sub>1</sub> is carbocyclic ring, R<sub>2</sub> is pyridyl, R' is as claimed , classified in class 546, subclass 329 and class 514, subclass 357.
  - II. Claims 3, 7, 10, 11, 12, 13, 14, 17-20, drawn to the formula I in claim 1 where the radicals R<sub>1</sub>-R<sub>4</sub>, R', and R'', A, and B are all other moieties not claimed in group, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

In the instant case, the different inventions have achieved a separate status in the art, have separate fields that aren't coextensive, and are capable of supporting separate patents. Further, a prior art reference that would anticipate the claims under 35 U. S. C. 102 (b) would not render obvious the same claim (s) under 35 U. S. C. 103 (a) with respect to another member. Searching the entire genus would be a burden on the USPTO in terms of time and expense. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

By virtue of the applicant's election of species which falls into group I, group I will be examined.

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The unelected portions of claims 1, 2, 4,5, 6, 8, 9, and 16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

If group II is pursued further in a divisional application, it may be subject to further restriction.

5. Claim 24 provides for the use of the compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 24 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). The recitation of the term, "use" is non-statutory. The claims should be directed to a compound.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4,5, 6, 8, 9, 15, 16, 21, 23-25 are rejected under 35 U. S. C. 112, first paragraph, because the specification, does not reasonably provide enablement for R1 or R2 equal to all mono- or polycyclic groups, mono or poly heterocyclic groups, aralkyl groups, or a hetero-

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alkyl groups which may be optionally substituted as claimed in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f. 2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 Wands factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Inter 1986).

Claim 24 is rejected under 35 U. S. C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. There is no reasonable assurance that these compounds will have all of the alleged properties or have the applicants supplied the data. The applicant is referred to *In re Fouche* 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is referred to *In re Wands*, 858 f. 2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Inter. 1986).

Claim 25 is rejected under 35 U. S. C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of treating all of the various respiratory disorders claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope

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with these claims. The claims as recited are broader than the scope of enablement. The applicant is referred to *In re Wands*, 858 f. 2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Inter 1986).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4,5, 6, 8, 9, 15, 16, 21, 23-25 are rejected under 35 U. S. C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 1, 2, 4,5, 6, 8, 9, and 16, the terms "mono- or polycyclic groups, mono or poly heterocyclic groups, aralkyl groups, or a hetero-alkyl groups" are indefinite. These terms are so broad as to render the claim meaningless.

B. In claim 21, there is no reference to an "effective amount" of this pharmaceutical composition being delivered to a host in need thereof.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2, 4, 5, 6, 8, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Morisawa et. al. (See Reference N) Morisawa et. al. teaches the instant compound Propanedioic acid, (4-fluorophenyl)(3-pyridinylmethyl)-,diethyl ester. At pages 1-111, see the instant compound.

9. The elected species appears to be allowable

Claim 22 appears to be missing from the amendment filed at paper no. 5.

10. The IDS filed 5/15/01 has been considered.

11. The reference noted as an X reference on the international search report may be an X reference but appears to not fall into the examined subject matter.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers are for the organization where this application or proceeding is assigned are (703) 308-7922 for regular communications and (703)308-7922 for After Final Communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-3082233.



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Binta Robinson

9/8/01

*Alan L. Rotman*

ALAN L. ROTMAN  
PRIMARY EXAMINER